Complete Summary

GUIDELINE TITLE

Hepatitis C. Sexually transmitted diseases treatment guidelines 2002.

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention. Hepatitis C. Sexually transmitted diseases treatment guidelines. MMWR Recomm Rep 2002 May 10;51(RR-6):64-6.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Hepatitis C

GUIDELINE CATEGORY

Diagnosis
Management
Prevention
Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Health Care Providers
Managed Care Organizations
Physicians

GUIDELINE OBJECTIVE(S)

- To update the 1998 Guidelines for Treatment of Sexually Transmitted Diseases (MMWR 1998;47[No. RR-1])
- To assist physicians and other health-care providers in preventing and treating sexually transmitted diseases (STDs)
- To present recommendations on the diagnosis, treatment, and prevention of hepatitis C

TARGET POPULATION

Persons infected with hepatitis C and persons seeking care in a sexually transmitted diseases (STD) clinic or other primary-care setting that also have the following risk factors:

- Illegal injection drug use, even once or twice many years ago
- Recipient of blood transfusion or solid organ transplant before July 1992
- Recipient of clotting factor concentrates produced before 1987
- Long-term hemodialysis

INTERVENTIONS AND PRACTICES CONSIDERED

Note from the National Guideline Clearinghouse and the Centers for Disease Control and Prevention: These guidelines focus on the treatment and counseling of individual patients and do not address other community services and interventions that are important in sexually transmitted disease/human immunodeficiency virus (STD/HIV) prevention.

Diagnosis

1. Detection of antibodies to hepatitis C virus (anti-HCV) using enzyme immunoassay (EIA) test
2. Detection of anti-HCV using recombinant immunoblot assay (RINA) for all positive anti-HCV results (by enzyme immunoassay)
3. Detection of hepatitis C virus ribonucleic acid (HCV RNA) by reverse transcriptase polymerase chain reaction (RT-PCR)

[Note: Reverse transcriptase polymerase chain reaction assays are not currently approved by the Food and Drug Administration.]

Treatment/Management

1. Alpha interferon with or without oral agent ribavirin for chronic liver disease

Primary prevention (reduces or eliminates transmission)

1. Counseling illegal injection drug users to stop using and enter treatment program
2. Counseling illegal injection drug users who are unable to stop how to inject safely
3. Counseling persons with multiple sex partners on how to reduce the transmission of sexually transmitted diseases (e.g., through abstinence or by decreasing the number of sex partners)

Secondary prevention (for hepatitis C-infected individuals)

1. Provide information on how patients can protect their liver from further harm (avoid alcohol, avoid taking new medicines without checking with doctor, become vaccinated against hepatitis A and B)
2. Provide information on how patients can prevent transmission to others (advise not to donate blood, body organs, other tissue, or semen, and not to share any personal items that may have blood on them, such as toothbrushes or razors)
3. Instruct patients about the importance of medical evaluation for chronic liver disease and possible treatment
4. Post-exposure follow-up

MAJOR OUTCOMES CONSIDERED

- Prevalence of hepatitis C virus infection
- Risk for infection
- Prevention of sequelae (e.g., chronic liver disease)
- Prevention of transmission

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Subjective Review

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Beginning in 2000, Centers for Disease Control and Prevention (CDC) personnel and professionals knowledgeable in the field of sexually transmitted diseases (STDs) systematically reviewed literature (i.e., published abstracts and peer-reviewed journal articles) concerning each of the major STDs, focusing on information that had become available since publication of the 1998 Guidelines for Treatment of Sexually Transmitted Diseases. Background papers were written and tables of evidence constructed summarizing the type of study (e.g., randomized controlled trial or case series), study population and setting, treatments or other interventions, outcome measures assessed, reported findings, and weaknesses and biases in study design and analysis. A draft document was developed on the basis of the reviews.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Hepatitis C virus (HCV) infection is the most common chronic bloodborne infection in the United States; an estimated 2.7 million persons are chronically infected. More than two thirds of all infected persons are aged <50 years. Persons with acute HCV infection typically are either asymptomatic or have a mild clinical illness. The average time from exposure to seroconversion is 8--9 weeks, and antibodies to HCV (anti-HCV) can be detected in >97% of persons by 6 months after exposure. Chronic HCV infection develops in most persons (75%--85%) after

acute infection; 60%--70% have evidence of active liver disease. Most infected persons may not be aware of their infection because they are not clinically ill. However, infected persons serve as a source of transmission to others and are at risk for chronic liver disease or other HCV-related chronic diseases for at least 2 decades after infection.

HCV is most efficiently transmitted by direct percutaneous exposure to infected blood (e.g., by receipt of blood transfusion from an infected donor or through use of injection drugs). Although less efficient, occupational, perinatal, and sexual exposures also can result in transmission of HCV. No association has been documented between HCV and military service or HCV and exposures resulting from medical, dental, or surgical procedures; tattooing; acupuncture; ear piercing; or foreign travel.

The greatest variation in prevalence of HCV infection occurs among persons with different risk factors for infection. The highest prevalence of infection is found among those with substantial or repeated direct percutaneous exposures to blood (e.g., injection drug users (IDU), persons with hemophilia treated with clotting factor concentrates produced before 1987, and recipients of transfusions from HCV-positive donors). Moderate prevalence is found among persons with frequent but limited direct percutaneous exposures (e.g., long-term hemodialysis patients). Lower prevalence occurs among persons with inapparent percutaneous or mucosal exposures or sexual exposure and among those with limited, sporadic percutaneous exposures (e.g., health-care workers). Lowest prevalence of HCV infection is found among persons with no high-risk characteristics (e.g., blood donors).

Sexual Activity

Although the role of sexual activity in the transmission of HCV remains controversial, results from several types of studies indicate that sexual activity is associated with HCV transmission. These studies reported independent associations between HCV infection and a) exposure to an infected sex partner, b) increasing numbers of partners, c) failure to use a condom, d) history of sexually transmitted disease (STD), e) heterosexual sex with a male injection drug user, and f) sexual activities involving trauma.

In contrast, a low prevalence (average: 1.5%; range: 0%--4.4%) of HCV infection has been demonstrated in studies of long-term spouses of patients with chronic HCV infection who had no other risk factors for infection. One study has found an association between HCV infection and male homosexual activity, and at least in STD clinic settings, the prevalence rate of HCV infection among men who have sex with men (MSM) generally has been similar to that of heterosexuals. Because sexual transmission of bloodborne viruses is more efficient among homosexual men compared with heterosexual men and women, it is unclear why HCV infection rates are not substantially higher among MSM compared with heterosexuals. This observation and the low prevalence of HCV infection observed among the long-term steady sex partners of persons with chronic HCV infection have raised doubts about the importance of sexual activity in the transmission of HCV. Unacknowledged percutaneous exposures (i.e., illegal injection-drug use) might contribute to increased risk for HCV infection among such persons.

Although inconsistencies exist between studies, data indicate overall that sexual transmission of HCV can occur and accounts for up to 20% of HCV infections. The substantial contribution of sexual transmission to the disease burden in the United States relative to the inefficiency with which the virus appears to be spread in this manner can be explained. Because sexual activity with multiple partners is a common behavior among chronically infected persons and because of the substantial number of these persons, multiple exposure opportunities exist. However, more data are needed to determine the risk for, and factors related to, transmission of HCV between sex partners, including whether other STDs promote the transmission of HCV by influencing viral load or modifying mucosal barriers.

Increased HCV viral load or coinfection with human immunodeficiency virus (HIV) (known to increase perinatal transmission of HCV) may increase the risk for sexual transmission. A recent study involving hemophilic men demonstrated that dually infected men had a higher HCV load than those infected with HCV alone, and that a higher HCV load was associated, though not significantly, with an increased risk for HCV transmission to female partners.

Diagnosis and Treatment

The diagnosis of HCV infection can be made by detecting either anti-HCV or HCV ribonucleic acid (RNA). Anti-HCV is recommended for routine testing of asymptomatic persons and should include use of both enzyme immunoassay (EIA) to test for anti-HCV and a supplemental antibody test (i.e., recombinant immunoblot assay [RIBA]) for all positive anti-HCV results. In settings where clinical services for liver disease are provided, use of reverse transcriptase polymerase chain reaction (RT-PCR) to detect HCV RNA might be appropriate to confirm the diagnosis of HCV infection (e.g., in patients with abnormal alanine aminotransferase [ALT] levels or with indeterminant supplemental anti-HCV test results), although reverse transcriptase polymerase chain reaction assays are not currently Food and Drug Administration (FDA)-approved.

Current approved therapy for HCV-related chronic liver disease includes alpha interferon alone or in combination with the oral agent ribavirin for a duration of 6--12 months. Because of advances in the field of antiviral therapy for chronic hepatitis C, standards of practice might change, and clinicians should consult with specialists knowledgeable about this virus. The National Institutes of Health Consensus Development Conference Panel recommended that therapy for hepatitis C be limited to those patients with persistently elevated alanine aminotransferase levels, detectable HCV RNA, and histologic evidence of progressive disease (as characterized by liver biopsy findings indicating either portal or bridging fibrosis or at least moderate degrees of inflammation and necrosis).

Prevention

No vaccine for hepatitis C is available, and prophylaxis with immune globulin is not effective in preventing HCV infection after exposure. Reducing the burden of HCV infection and disease in the United States requires implementation of both primary and secondary prevention activities. Primary prevention reduces or eliminates HCV transmission; secondary prevention activities reduce liver and other chronic diseases in HCV-infected persons by identifying them and providing

appropriate medical management and antiviral therapy, if necessary. Persons seeking care in STD clinics or other primary-care settings should be screened for risk factors for HCV infection, and those with the following risk factors should be offered counseling and testing:

- illegal injection drug use, even once or twice many years ago
- blood transfusion or solid organ transplant before July 1992
- receipt of clotting factor concentrates produced before 1987
- long-term hemodialysis

Regardless of test results, persons who use illegal drugs or have multiple sex partners should be provided with information regarding how to reduce their risk for acquiring bloodborne and sexually transmitted infections and how to avoid transmitting infectious agents to others (e.g., through vaccination against hepatitis B and, if appropriate, hepatitis A). Persons who inject drugs should be counseled to stop using and get into a treatment program. If they are found at any follow-up visit to be continuing the use of these drugs, they should be counseled on how to inject safely (i.e., use of sterile, single-use equipment, including needles, syringes, cookers, cottons, and water each and every time they inject). Persons with multiple sex partners should be counseled regarding how to reduce the transmission of STDs (e.g., through abstinence or by decreasing the number of sex partners).

Persons who test negative for HCV who had a previous exposure should be reassured that they have not been exposed. Persons who test positive for HCV infection should be provided information regarding how to protect their liver from further harm, how to prevent transmission to others, and the need for medical evaluation for chronic liver disease (CLD) and possible treatment. To protect their liver from further harm, HCV-positive persons should be advised to avoid alcohol, avoid taking any new medicines (including over-the-counter and herbals) without checking with their doctor, and become vaccinated against hepatitis A or hepatitis B if they are not immune. To reduce the risk for transmission to others, HCV-positive persons should be advised not to donate blood, body organs, other tissue, or semen and not to share any personal items that may have blood on them (e.g., toothbrushes and razors).

HCV-positive persons with one long-term, steady sex partner do not need to change their sexual practices. They should discuss the low but present risk for transmission with their partner and discuss the need for counseling and testing. HCV-positive women do not need to avoid pregnancy or breastfeeding.

Postexposure Follow-Up

No postexposure prophylaxis is effective against HCV. Testing to determine whether HCV infection has developed is recommended for health-care workers after percutaneous or permucosal exposures to HCV-positive blood and for children born to HCV-positive women.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

Throughout the 2002 guideline document, the evidence used as the basis for specific recommendations is discussed briefly. More comprehensive, annotated discussions of such evidence will appear in background papers that will be published in a supplement issue of the journal Clinical Infectious Diseases.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Primary prevention activities reduce risks for contracting hepatitis C viral infection
- Secondary prevention activities reduce risks for chronic liver disease in hepatitis C virus infected persons and reduce the risk for transmission to others
- Appropriate diagnosis and management of hepatitis C virus infection

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These recommendations were developed in consultation with public- and private-sector professionals knowledgeable in the treatment of patients with sexually transmitted diseases (STDs). They are applicable to various patient-care settings, including family planning clinics, private physicians' offices, managed care organizations, and other primary-care facilities. When using these guidelines, the disease prevalence and other characteristics of the medical practice setting should be considered. These recommendations should be regarded as a source of clinical guidance and not as standards or inflexible rules. These guidelines focus on the treatment and counseling of individual patients and do not address other community services and interventions that are important in sexually transmitted disease/human immunodeficiency virus (STD/HIV) prevention.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention. Hepatitis C. Sexually transmitted diseases treatment guidelines. MMWR Recomm Rep 2002 May 10;51(RR-6):64-6.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1993 (revised 2002 May 10)

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

GUIDELINE DEVELOPER COMMENT

These guidelines for the treatment of patients who have sexually transmitted diseases (STDs) were developed by the Centers for Disease Control and Prevention (CDC) after consultation with a group of professionals knowledgeable in the field of STDs who met in Atlanta on September 26--28, 2000.

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

The information in this report updates the "1998 Sexually Transmitted Diseases Treatment Guidelines" (MMWR 1998;47[No. RR-1]).

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML version
- Portable Document Format (PDF)

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Workowski KA, Levine WC, Wasserheit JN. U.S. Centers for Disease Control and Prevention guidelines for the treatment of sexually transmitted diseases: an opportunity to unify clinical and public health practice. Ann Intern Med. 2002 Aug 20;137(4):255-62. Electronic copies: Available through Annals of Internal Medicine Online.
- Sexually Transmitted Diseases Treatment Guidelines 2002 for PDA or Palm OS. Available from the CDC National Prevention Information Network (NPIN) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on September 5, 2002.

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